DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region 93401d

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6008

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 3, 2002

File # 02-NWJ- 24

Mr. Frank Pulini Sr.
President
Pulini, Inc.
1100 Ferry Avenue
Camden, NJ 08104

Dear Mr. Pulini:

Investigators from the Food and Drug Administration (FDA) inspected your firm, located at 1100 Ferry Avenue, Camden, New Jersey on May 24, 31 and June 3, 2002, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention during past inspections, cause your smoked whitefish, ready-to-eat (RTE) whitefish salad,and pasteurized canned crabmeat to be adulterated within the meaning of Section 402(a)(4) of the Federal Food Drug & Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations found were as follows:

- Your firm does not have written HACCP plans for smoked whitefish and whitefish salad, both of which are RTE foods. In order to comply with 21 CFR 123.6(b), you must have written HACCP plans to control the potential food safety hazard of pathogen growth for these products. Your firm's receiving logs showed that you received and stored smoked whitefish and whitefish salad regularly from November 1, 2001, to the present.

- You must fully document, in record form, all corrective actions taken in order to comply with 21 CFR 123.7(d). However, your firm did not document that a

corrective action was taken when your continuous temperature recording device recorded temperatures consistently ranging from 44 to 46 ^{0}F on April 16, 2002, from 6:00 AM to approximately 8:00 PM. During that time period, the receiving records collected by our investigator indicate that your firm received and subsequently stored a potentially hazardous product, whitefish salad. Similarly, your continuous temperature recording device recorded temperatures ranging from a low of 42 ^{0}F to a high of 47 ^{0}F during the entire seven day period of November 8-15, 2002. During that time period, your receiving logs showed that you received and stored potentially hazardous products, including smoked whitefish and whitefish salad. The above referenced products are ready-to-eat foods, which must be maintained at $\leq$ 40 ^{0}F in order to control the food safety hazard of pathogen growth. However, your firm did not document that any corrective actions were taken in either instance.

- You must have a HACCP plan that lists adequate critical limits in order to comply with 21 CFR.123.6(c)(3). However, your HACCP plans for histamine producing species and pasteurized canned crabmeat do not list adequate critical limits at the receiving and storage critical control points. In both plans the critical limit is listed as "...temperature should never exceed forty-five degrees." Canned pasteurized crabmeat must be received and stored at $\leq$ 40 ^{0}F in order to control the food safety hazard of Clostridium Botulinum growth. Similarly, histamine producing fish must be received and stored at $\leq$ 40 ^{0}F in order to control the food safety hazard of histamine production. Further, your HACCP plans do not identify what factor is to be monitored, internal product temperatures or the ambient air temperatures in your cooler unit.
- You must adequately monitor sanitation conditions and practices at your firm and take appropriate corrective actions when warranted, in order to comply with 21 CFR 123.11(b). However, sanitation monitoring at your firm was either absent or inadequate. For example, your firm performed no sanitation monitoring from March 6 to May 24, 2002. Further, during the current inspection, our investigator observed actual sanitation deficiencies at the following key sanitation control points: (a) exclusion of pests (rodent pellets were observed in the dry goods storage area), (b) prevention of cross contamination (condensate from overhead pipes was observed dripping onto bagged potatoes and onto butcher paper used to wrap product), and; (c) safety of water (the ice machine's interior was soiled and came into direct contact with ice. Said ice was then placed directly on top of food products). Your firm's lack of sanitation monitoring was previously brought to your attention during our inspection of November 15, 2000.

We may take further regulatory action if you do not promptly correct these violations. Such actions may include seizure of your product(s) and/ or injunction.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, revised monitoring procedures, copies of revised monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when the corrections will be completed.

This letter may not list all deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations in Part 123 and the Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act and all applicable regulations.

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Compliance Officer at the address and telephone number listed above.

Sincerely,

Douglas I. Ellsworth

Douglas I. Ellsworth
District Director
New Jersey District